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| 7590 | 06/30/2009 | | EXAMINER | |
| Patrick W. Rasche Armstrong Teasdale LLP Suite 2600 One Metropolitan Square St. Louis, MO 63102 | | | ROZANSKI, MICHAEL T | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/809,117 | KATO, SEI | |
| | Examiner | Art Unit | |
| | MICHAEL T. ROZANSKI | 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 May 2009.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jago et al (US 5,938,607) in view of Hao et al (US 6,984,211) or Lobregt (US 5,559,901) or Murashita (US 6,878,114).

Jago et al disclose an ultrasonic imaging system provided to aid in the diagnosis of patient conditions by providing access from the ultrasound system to a library of reference ultrasonic images. The image library is catalogued in accordance with an image characteristic such as the type of examination, the part of the body, or the type of pathology shown in the image, and the images of the library are accessed in accordance with these characteristics. The image library may be remotely located and accessible by a number of ultrasound systems over a network, or it may be located on the ultrasound system on a system disk drive. Preferably, reference images are concurrently displayed side-by-side (col 2, lines 37-40) with real-time patient images to aid in discerning the patient's condition (see Abstract). Such would also be useful in the training of new ultrasound system users (col 10, lines 34-36). Specifically, the ultrasound system 10 includes the conventional components including scanhead 14

with transducer 12. The beams of echo information are processed by a signal processor 64 in accordance with the type of diagnostic information that is obtained such as B mode or Doppler (col 2, lines 52-66). A browser 120 included with the ultrasound system 10 is compiled with software code which steers received system preset data to the appropriate area of the ultrasound system, where it can be utilized by the ultrasound system controller to control the functioning of the system. When the operator uses the browser to access system preset data from another ultrasound system or data storage device, the steering code directs the received system preset data to scan parameter storage 82, where it is stored as custom preset data. The ultrasound system controller 18 will then initialize the ultrasound system to perform ultrasonic scanning in accordance with the operator's custom system presets (col 7, lines 25-49).

Jago does not specifically describe automatically defining a region of interest. However, Hao et al teach of a method for automatically defining the boundary or edge of a tumor in an ultrasonic image. The method can be done manually or automatically (col 6, line 15-col 7, line 5). It would have been obvious to modify Jago, to include automatically defining a region of interest as taught by Hao et al, in order to extract useful clinical information or to characterize a tumor (col 2, line 52-col 3, line 2). Alternatively, Lobregt teaches a method and apparatus for automatically defining the outline of a region of interest, such as an organ or tumor, in a 2 or 3 dimensional image. This may be performed in a variety of images of clinical importance, including ultrasound images (col 1, lines 20-30). It would have been obvious to the skilled artisan to modify Jago, to include automatic defining of a region of interest as taught by

Lobregt, because the defined outline of the object can, for example, be used as a basis for providing quantitative information to a physician, for surface extraction, for visualization, or for volume definition (coil 1, lines 30-33). In yet another alternative, Murashita teaches of a ROI generator unit 90, wherein the ROI may be set manually or automatically (col 12, lines 34-48). It would have been obvious to modify Jago, to provide for defining a ROI as taught by Murashita, in order to simplify setting of a ROI within a 3D space (col 1, lines 12-30).

Claims 1, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jago et al (US 5,938,607) in view of Hao et al (US 6,984,211) or Lobregt (US 5,559,901) or Murashita (US 6,878,114), and further in view of Holloway et al (US 6,500,123).

Jago in view of Hao, Lobregt, or Murashita discloses the invention as described above. The combination features the Jago teaching that reference images are compared with real time images. Jago teaches reference images are those of a subject, but not explicitly of the same subject. Rather, the reference image is from a library located on the ultrasound system itself or on a disk. However, Holloway teaches of comparing ultrasound images before and after treatment in order to assess the efficacy of a given treatment for a disease. It would have been obvious to modify Jago in view of Hao/Lobregt/ or Murashita, to provide reference images of the same subject undergoing treatment as taught by Holloway, in order to assess the efficacy of the treatment for a specific subject, as opposed to diagnosing a subject based on a reference image from a general library.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jago et al and Hao or Lobregt or Murashita and Holloway as applied to claim 1 in view of Hossack et al (2002/0120195).

Jago et al and Hao or Lobregt or Murashita and Holloway substantially discloses the invention as claimed including displaying the images side-by-side but do not calculate a correlation coefficient between the images. Hossack et al teach of calculating a correlation coefficient that is further displayed [0168, 0176]. It would have been obvious to the skilled artisan to modify Jago et al and Hao or Lobregt or Murashita, to calculate and display a correlation coefficient as taught by Hossack et al, because such would be useful to the operator in comparing the images for diagnostic and/or training purposes.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jago et al and Hao or Lobregt or Murashita as applied to claim 9 in view of Hossack et al (2002/0120195).

Jago et al and Hao or Lobregt or Murashita in view of Hossack teach the claimed invention as described above.

Response to Arguments

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection, as the positive recitation of the "generating a reference image of a subject" changes the scope of the claim.

As an aside and in regard to claim 1, Applicant may want to include a step of providing medical treatment before acquiring the real-time image, as this would seem to more clearly define the invention.

In regard to claims 9-19, Applicant's arguments filed 5/19/09 have been fully considered but they are not persuasive. Applicant argues that the references (specifically Jago) does not disclose a scan condition storage device and an automatic scan condition setting device as claimed in claims 9 and 11. However, Examiner finds that the ultrasound system controller 18 initializes the system to perform scanning in accordance with the operator's custom system presets, as indicated by the connections between the controller 18 and the beamformer 16, signal processor 64, and display processor 68 (col 7, lines 43-49). The preset data is stored in scan parameter storage 82. As previously discussed, while the operator manipulates user controls to select custom preset data, the scan condition is still automatically set because the parameters are preset (i.e. system preset data). This is also considered to encompass the newly claimed "current scan condition."

It is noted that in the apparatus claims 9-19, there is no weight given to the limitations regarding "when" the medical treatment is provided, as the reference discloses all the structural limitations which are capable of being performed before/after any treatment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. ROZANSKI whose telephone number is (571)272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

MR